

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the claims

1. (currently amended) A drug formulation comprising

~~a drug selected from the group consisting danazol~~[[,]] ~~bromocriptine, and luteinizing hormone-releasing hormone (LHRH) analogues in an amount effective to provide regional~~
providing regionally effective, not systemic systemically effective, levels of danazol when
administered transdermally to the breast, to provide relief from benign diseases or disorders of
the breast,

wherein the danazol is formulated in a hydroalcoholic gel pharmaceutical carrier
comprising a transdermal penetration enhancer N-methyl-2-pyrrolidone or 2-pyrrolidone in an
effective amount to solubilize danazol and to promote delivery of the drug deliver danazol across
the stratum corneum to the underlying breast tissue.

2.-9. (cancelled)

10. (withdrawn, currently amended) A method for treating a disease or disorder of the
breast treatable with danazol comprising

topically administering to the breast of a patient,

a drug formulation ~~suitable for local or regional delivery~~ comprising an effective amount
of ~~drug selected from the group consisting of~~ danazol[[,]] ~~bromocriptine, and luteinizing~~
~~hormone-releasing hormone (LHRH) analogues,~~

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in an amount ~~effective to provide regional~~ providing regionally effective, not ~~systemic~~
systemically effective, levels of danazol when administered transdermally to the breast tissue, to
provide relief from benign diseases or disorders of the breast,

wherein the danazol is formulated in a hydroalcoholic gel pharmaceutical carrier
comprising a transdermal penetration enhancer N-methyl-2-pyrrolidone or 2-pyrrolidone in an
effective amount to solubilize danazol and to promote delivery of the drug deliver danazol across
the stratum corneum to the underlying breast tissue.

11-16. (cancelled)

17. (withdrawn, currently amended) The method of claim 10 wherein the benign disease
of the breast is selected from the group consisting of mastalgia, mastodynia, ~~Mondor's disease,~~
and fibrocystic breast disease, ~~costochondritis, mastitis, Paget's disease of the areola,~~
~~fibroadenoma, breast abscess, and breast infections.~~

18. (cancelled)

19. (withdrawn, previously presented) The method of claim 10 wherein the region is the
breast, areola, and underlying musculature of the chest.